
Renal Association Clinical Trials Sub-committee

Minutes

10th March 2004

Institute of Child Health, London

Present:

David Jayne (DJ, chair), Peter Mathieson (PM), Colin Baigent (CB), Jill Cooke (JC, research nurse at Royal Free Hospital), David Eadington (DE), Neil Iggo (NI), Colin Jones (CJ), Phil Kalra (PK), Keith Wheatley (KW).

1. Apologies for absence:

Apologies had been received from Jo Adu, Paramit Chawdry, Nick Webb and David Wheeler.

2. Minutes of last meeting:

These had been previously circulated by e-mail and were approved as a correct record.

3. Matters arising

4. Restructuring of Renal Association Subcommittees

The president has suggested two boards, clinical and academic, with this committee being under the latter. Some dissent (PM, CB, CJ, DE), importance of distinguishing this committee from basic/laboratory research and obvious connections with standards and registry that are in the clinical board. Concerns of committee to be raised at next executive meeting and 'ad hoc' meeting to be arranged by Caroline Savage. **DJ**

Request regular sessions, preferably twice a year, at RA meetings. **DJ**

5. European Clinical Trials Directive (Wheatley)

Reliable results more important than accurate data.

Clinical Trial Authorisations (CTA) required from May 1 2004.

MHRA interested in pragmatic trials.

Only affects drug trials.

New body to handle ethics 'COREC'.

Principle Investigator (PI) will be responsible for trial.

Outstanding concern over role of hospital R&D committees.

Pharmacovigilance will require reporting of Serious, Unexpected, Adverse Drug Reactions (SUSARS) (not in product characteristics)

6. ASTRAL (Kalra)

- 350 recruits, revised target 750. 55 LREC centres. Australia and New Zealand being chased. Substudy on echocardiograms and cardiac function changes.
7. SHARP (Baigent)
950 screened from 6 countries, 508 randomised. 6 regional co-ordinating centres. UK collaborators meeting 29/30 March 2004.
 8. Glomerulonephritis
 - a) Membranous nephropathy (Mathieson)
83 recruits. Target 120. Nurse funding to end 2006.
 - b) SLE & vasculitis (Jayne)
SLE Rituximab study from UK lupus trials group now taken in house by Roche and trials in lupus nephritis and extra-renal lupus being planned. IMPROVE vasculitis study with mycophenolate has recruited 120 of target 160. PI, Lorraine Harper invited to join committee.
 9. MERIT (Iggo)
About to be launched. Leeds will host trial co-ordination.
 10. Transplantation (CB)
RABIT. Successful grant application to NKRF (50k). Discussions with industry for the rest of the funding are stalled.
Development of non-heating beating donor project.
 11. New Trial Proposals
 - a) the impact of antioxidant therapy on CV endpoints in CKD patients (Baigent)
An interesting proposal from Morris Jackson but to be successful would have to be very large (SHARP – like) generally unenthusiastic.
 - b) phase II trial of a new direct thrombin inhibitor in haemodialysis patients (Guy Patrick, CRC development)
A request from industry for interested centres to study a novel synthetic thrombin inhibitor.
 - c) phase I trial of APT070 in atypical HUS (not discussed)
 - d) Treatment of Restless Legs syndrome (Coralie Bingham, Bristol)
Referred for advice to **KW**
 12. Any other business
 - a) Following discussions with NKRF, there is a need for the development of guidelines for the assessment of clinical trial projects and clinical research fellowship applications. **DJ**
 13. Date of next meeting
 - a) To be confirmed
 - b) Possible open renal clinical trials meeting in March 2005, repeat of successful 2003 meeting
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